**APPLICATION TO INTRODUCE A NEW PROCEDURE, TECHNIQUE OR MAJOR CHANGE IN CLINICAL PRACTICE WITHIN SALISBURY NHS FOUNDATION TRUST**

**ESTABLISHING THE CLINICAL CASE**

This form is available electronically from MicroGuide at:

<https://viewer.microguide.global/guide/1000000295#content,f2093345-2006-4639-9a63-3702fbc82cfb>

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| 1.  1.1  1.2 | Name of applicant – *should be Health Professional intending to carry out new procedure/technique*  Name of Department /  Division  Extension numbers |  |
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| 2.  2.1  2.2 | Title of new procedure/technique  Brief description of what is involved in the procedure/technique  Is this procedure for children |  |
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| Yes No  Yes / No |
| 3. | NICE status - please tick: see www.nice.org.uk/guidance  *Refer to page 5 and Appendix 2 of policy* | **A:** **NICE approved guidance issued –**  safety and efficacy appears adequate for  use with the normal arrangements for  consent, audit and clinical governance  **B:** **Part of an approved research**  **programme** – requires approval  by the R&D Dept and HRA  (please visit   * <http://www.salisbury.nhs.uk/InformationForPatients/Departments/Research/Pages/IndexPage.aspx> * <https://www.hra.nhs.uk/>   or  **C: Requires special arrangements**  for audit/evaluation in accordance with  NICE requirements  **D: No guidance issued**  **E:** **If none of the above** please state - |
| 4.  4.1  4.2 | Has this proposed new procedure/technique previously been performed:  At Salisbury Foundation NHS Trust  Has this proposed new procedure/technique previously been observed and performed by the applicant? | Yes No  Yes No  If yes, by whom?  Yes No  If yes, where?  How many times  performed?  performed?  How many  times observed?  Records available  Yes No | |
| 5.  5.1 | Is research evidence available regarding the effectiveness/safety of this new procedure/technique?  Please state if appropriate:   1. Research paper reference(s) 2. NHS Evidence 3. NICE Guidance *(title and number)* | Yes No  If yes, please complete 5.1 | |
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| 6. | Has the proposed procedure/technique/drug been discussed with: | Medical Devices Committee:  Yes (attach Minutes) No  Procurement Department  Yes (attach Minutes) No  Drugs and Therapeutics Committee  Yes (attach Minutes) No  All appropriate Clinical Directors – especially in the case of multi-professional working:  Yes No  If yes, please list:    Other relevant colleagues – internal and external to Trust: e.g. Diagnostics, CCG  Yes No  If yes, please list: | |
| 7. | Please describe the benefits to the patient: |  | |
| 8. | Please describe any risks to the patient: |  | |
| 9. | What are the additional training requirements and for whom?  How will these be met?  How will these be met? |  | |
|  | |
| 10. | Has the practitioner undertaking the procedure met externally set standards of training, if available?  Details of external training: | Yes No | |
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| 11. | What are the additional competencies required and for whom?  How will these be met? |  | |
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| 12. | Are there any workforce implications for the team involved?  e.g. grading issues, skill mix changes, number of staff required? | Yes No  If yes, please state: |
| 13. | Please describe the proposed informed consent process to be put in place: |  |
| 14. | Please describe the proposed audit/evaluation plan, including measures and frequency of reporting:  **NB. The Trust will monitor the completion of these and expect an audit within a year of the introduction of the practice** |  |
| 15. | Is this new procedure/technique included in the Trust or Divisional service  plan?  If yes, is a business case required to progress this new procedure (see appendix 2 on how to write a business case) | Yes No  Yes (attach) No |
| 16. | Signatures required to validate the Clinical Case:  Lead Clinician Approved: Yes No  ……………………………………………………………………….. Date: …………………………………..  Clinical Director Approved: Yes No  ……………………………………………………………………….. Date: …………………………………..  Divisional Manager Approved:  Yes No  ……………………………………………………………………….. Date: …………………………………..  Divisional Finance Manager approved: Yes No  ……………………………………………………………………….. Date: …………………………………..  Medical Director Approved: Yes No  ……………………………………………………………………….. Date: ………………………………….. | |

KEEP MASTER COPY

Return COPY to Head of Clinical Effectiveness, Block 24, Quality Directorate, SDH for inclusion on ‘New procedures’ database

Contact Executive Services Manager for agenda item on Trust Management Committee.

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| *For Office Use only:*   * Audit data due: ……………………………… (date) Audit Dept aware * Patient information checked (must include risks, benefits and alternatives) * Patient information available on MicroGuide * Local protocols / guidelines written, approved and on MicroGuide * Competency of practitioner agreed   Evidence kept: …………………………………………   * To Trust Management Committee for approval   Date: …………………………………………….   * Divisional Manager and Lead Clinician to include in Service Plan * TMC Approved procedure added to New Procedures database   Date: ………………………………………………….   * Director of Corporate Development aware |